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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/786,322 | 02/25/2004 | Daniel M. Lafontaine | 10527-437002 | 2641 |

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| EXAMINER | |
|---|---|
| VRETTAKOS, PETER J | |
| ART UNIT | PAPER NUMBER |
| 3739 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/786,322 | LAFONTAINE, DANIEL M. | |
| | Examiner | Art Unit | |
| | Peter J. Vrettakos | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *43,44,46,47,49,50,52,54-55 and 57-63* is/are pending in the application.

4a) Of the above claim(s) *55 and 57-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43,44,46,47,49,50,52 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**The action is final as necessitated by amendment.**

**An election was made 2-9-07 without traverse to claims 43-44,46-47,49-50,52 and 54. Claims 55 and 57-63 are withdrawn.**

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 43, 44, 46, 49, 50, 52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (6,027,499).**

Johnston et al. (6,027,499) discloses a minimally invasive device (10) and method of use comprising a tubular member (20), a retractable cryotherapy apparatus (46) with an inner chamber (20 in fig. 2) and an outer chamber (46 in figure 2), and an optical sensor/imaging apparatus (14) defined within a lumen defined in the tubular member used to monitor temperatures of the targeted region (col. 7:65-67) and monitor ice formation ("frost", col. 7:65-67). Johnston discloses temperature sensors (92, figure 12b) and a "quantification" device (28, figure 12a, 99, figure 6) in communication with the optical sensor (monitor 28 and device 99 are included in the same cryosurgical system depicted in figure 6 with both elements 28 and 99 providing the surgeon concurrent information during the procedure).

With regards to the Johnston et al. making obvious an apparatus sized for vascular introduction, the MPEP provides guidance to Examiners with regards to changes in size of patented inventions. MPEP § 2144.04 reads:

"IV. CHANGES IN SIZE, SHAPE, OR SEQUENCE OF ADDING INGREDIENTS

A. Changes in Size/Proportion

In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device."

In light of the MPEP guidance provided to the Examiner, notwithstanding the fact that the case law is fact specific, he cannot fairly state that shrinking the Johnston device for vascular use would not have been obvious.

**Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (6,027,499) in view of Joye et al. (6,355,029).**

*Johnston neglects to expressly disclose retractable optical temperature sensors.*

Joye discloses an analogous cryotherapy apparatus with retractable (see figure 7 double sided arrow in balloon 18) temperature sensors (24) partially disposed in a lumen (20) defined in a tubular member (12), and a balloon (cryo therapy apparatus) with inner (see figure 5, 60) and outer chambers (inside 58). Joye also discloses a temperature feedback controller (134) in figure 13.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Johnston in view of Joye by including the balloon design. The motivation would be to afford vascular cryogen applications with a balloon and a retractable sensing device to the Johnston device.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Williams et al. (6,468,297).

***Response to Arguments***

Applicant's arguments filed 2-9-07 have been fully considered but they are not persuasive. The Applicant points out that the optical fiber in Johnston is separate from the cooling device unlike that in the claims 43 and 52. Regardless is Johnston's optical is separate, claims 43 and 52 do not include language toward a sensor being a part of the same device as the cooling device.

The Applicant's arguments/opinions against the appropriateness of reducing the size of the Johnston invention are conjectural and provide the Examiner with insufficient reasons to preclude application of MPEP 2144.04(IV)(A), which effectively states that changes in size of patented invention by an Applicant are not patentably distinct from the patented invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Roy D. Gibson

ROY D. GIBSON
PRIMARY EXAMINER

Pete Vrettakos
May 8, 2007